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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,296	02/15/2007	Jonathan E. Britton	PR60351USW	7071

23347 7590 07/08/2008

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EXAMINER	
OH, TAYLOR V	

ART UNIT	PAPER NUMBER
1625	

NOTIFICATION DATE	DELIVERY MODE
07/08/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/565,296	BRITTON ET AL.	
	Examiner	Art Unit	
	Taylor Victor Oh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26,28,40 and 42-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26,28,40 and 42-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/08 & 1,6/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The Status of Claims:

Claims 26, 28, 40, and 42-52 are pending.

Claims 26, 28, 40, and 42-52 are rejected.

DETAILED ACTION

1. Claims 26, 28, 40, and 42-52 are under consideration in this Office Action.

Priority

2. It is noted that this application is a 371 of PCT/US04/24308 (07/27/04), which has a priority document, USA 60490588(07/28/2003).

Drawings

3. None.

Claim Objections

Claim 26 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 42. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 42 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 26. When two claims in an application are duplicates or else are so close in

content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the specific reaction temperature range and the specific reagents during the process of making the desired products.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

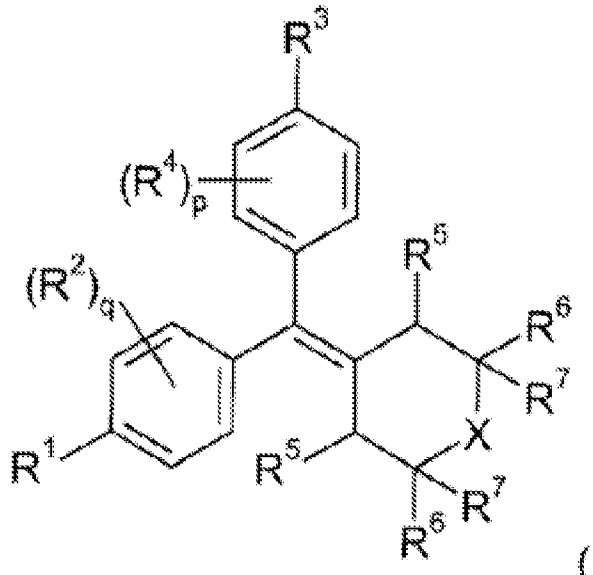
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26, 28, 40, and 42-52 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2,4-21,25,28,39-46 of copending Application No. 11/748,096. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the relationship between the genus and the species.

The claims 1 and 25 of copending Application No. 11/748,096 is described below:

1. (Currently Amended) A compound of formula (I):



(I)

,

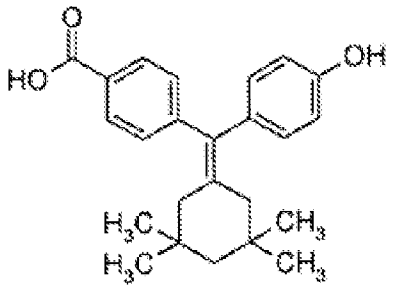
and

4-[(4-Hydroxyphenyl)(3,3,5,5-tetramethylcyclohexylidene) methyl]benzoic acid

,

whereas the claim 26 of the instant invention is shown below:

26. (Currently Amended) A compound of the formula



,

or a pharmaceutically acceptable salt thereof ~~including salts, solvates, and pharmacologically functional derivatives thereof~~.

However, the instant invention differs from the copending application in that the claims of the co-pending application have the compounds with a broad genus, whereas the claims of the instant invention is a single species of the claimed compound.

Even so, claim 25 discloses the same compound as the instantly claimed compound and the rest of the instant claims are very closely related to those claims of the co-pending application. Therefore, it would have been obvious to the skilled artisan in the art to be motivated to modify those claims of the co-pending application to narrow its limitation so as to accentuate the preferred embodiment for the claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 43-51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being not enabling for the method for treating a condition or disease selected from osteoporosis, osteoarthritis, breast cancer , rheumatoid arthritis, vasomotor symptoms, vulvar vaginal atrophy, and obesity in a mammal thereof comprising administering to a therapeautically effective amount of a compound according to claim 26. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The Nature of the Invention

The nature of the invention in claims 43-51 is related to the method for treating a condition or disease selected from osteoporosis, osteoarthritis, breast cancer , rheumatoid arthritis, vasomotor symptoms, vulvar vaginal atrophy, and obesity in a mammal thereof comprising administering to a therapeautically effective amount of a compound according to claim 26.

The State of the Prior Art

The state of the prior art are in the followings:

Estrogens are well-known endocrine regulators in the cellular processes involved in the development and maintenance of the reproductive system. Estrogens have also been shown to have important effects in many non-reproductive tissues such as bone, liver, the cardiovascular system, and the central nervous system. The most widely accepted hypothesis of how estrogens exert their effects is by binding to an intracellular steroid hormone receptor. After the receptor and bound ligand are transferred to the nucleus of the cell, the complex binds to recognition sites in DNA, which allows for the modulation of certain genes. Additionally, it is now becoming apparent that estrogens may mediate their effects via membrane-initiated signaling cascade, though much of this work is still experimental. Kousteni et al., *Journal of Clinical Investigation*, (2003), *111*, 1651–1664, herein incorporated by reference with regard to such teaching.

Certain substances have demonstrated the ability to exhibit their biological activity in a "tissue-selective" manner. In other words, tissue selectivity allows functionality as estrogen agonists in certain tissues, while acting as estrogen antagonists in other tissues. The term "selective estrogen receptor modulators" (SERMs) has been given to these molecules. Examples of SERMs include tamoxifen, raloxifene, lasofoxifene, clomiphene, and nafoxidine. The molecular basis for this tissue-selective activity is not completely understood. Without being limited to any particular theory, the ability of the ligand to place the estrogen receptor into different conformational states and allowing for differential capabilities in recruiting coactivator and corepressor proteins, as well as other important proteins involved in transcriptional regulation, is believed to play a role. See, McDonnell, D. P., *The Molecular Pharmacology of SERMs*, Trends Endocrinol. Metab. 1999, 301–311, herein incorporated by reference with regard to such description.

Historically estrogens were believed to manifest their biological activity through a single estrogen receptor, now termed estrogen receptor alpha (ERα). More recently, however, there was the discovery of second subtype of estrogen

receptor, termed estrogen receptor beta (ERβ). See, Kuiper et al., WO 97/09348 and Kuiper et al., *Cloning of a Novel Estrogen Receptor Expressed in Rat Prostate and Ovary*, Proc. Natl. Acad. Sci. U.S.A., 1996, pp. 5925–5930, herein incorporated by reference with regard to such subtype. ERβ is expressed in humans. See, Mosselman et al., *ERβ: Identification and Characterization of a Novel Human Estrogen Receptor*, FEBR S Lett., 1996, pp. 49–53, herein incorporated by reference with regard to such expression. The discovery of this second subtype of estrogen receptor significantly increased the biological complexity of estrogen signaling and may be responsible for some of the tissue-selective actions of the currently available SERMs.

As noted above, estrogens have important effects in many non-reproductive tissues. Thus, estrogen modulation is believed useful in the treatment or prophylaxis of diseases and conditions associated with such tissues, including bone, liver, and the central nervous system. For example, osteoporosis is characterized by the net loss of bone mass per unit volume. Such bone loss results in a failure of the skeleton to provide adequate structural support for the body, thereby creating an increased risk of fracture. One of the most common types of osteoporosis is postmenopausal osteoporosis, which is associated with accelerated bone loss subsequent to cessation of menses and declining levels of endogenous estrogen in women. There is an inverse relationship between densitometric measures of bone mass and

fracture risk, for peri- and postmenopausal women in the process of rapid bone loss due to declining levels of estrogen. See, Stemenda, et al., *Predictors of Bone Mass in Perimenopausal Women, A Prospective Study of Clinical Data Using Photon Abr sorptiometry,* Ann. Intern. Med., 1990, pp. 96–101 and Marshall, et al., *Meta-Analysis of How Well Measures of Bone Mineral Density Predict Occurrence of Osteoporotic Fractures,* Br Med. J., 1996, pp. 1254–1259, each of which is herein incorporated by reference with regard to such relationship. Elderly women currently have a lifetime risk of fractures of about 75%. In addition there is an approximate 40% risk of hip fracture for Caucasian women over age 50 in the United States. The economic burden from osteoporotic fractures is considerable because of the necessity of hospitalization. In addition, although osteoporosis is generally not thought of as life-threatening, the mortality within 4 months of hip fracture is currently approximately 20 to 30%. Current therapies for postmenopausal osteoporosis include hormone replacement therapy or treatment with other antiresorptive agents such as bisphosphonates or calcitonin. Similarly, SERMS have been shown to be effective in the treatment of postmenopausal osteoporosis (see, Lindsay, R.: *Sex steroids in the pathogenesis and prevention of osteoporosis.* In: Osteoporosis 1988. Etiology, Diagnosis and Management. Riggs BL (ed)l, Raven Press, New York, USA (1988):333–358; Barzel US: *Estrogens in the prevention and treatment of postmenopausal osteoporosis*: a review. *Am J. Med* (1988) 85:847–850; and Ettinger, B., Black, D.M., et al., *Reduction of Vertebral Fracture Risk in Postmenopausal Women with Osteoporosis Treated with Raloxifene, JAMA,* 1999, 282, 637–645, each of which is incorporated by reference with regard to such teaching).

As another example, the effects of estrogens on breast tissue, particularly breast cancer, have been well documented. For example, a previously identified SERM, tamoxifen, decreases the risk of recurrent breast cancer, contralateral breast cancer, and mortality as well as increases the disease-free survival rate of patients with breast cancer at multiple stages of the disease. See, Cosman, F., Lindsay, R. *Selective Estrogen Receptor Modulators: Clinical Spectrum*, Endocrine Rev., 1999, pp. 418–434, herein incorporated by reference with regard to such teaching. The profile of tamoxifen, however, is not ideal due to potential interactive properties on reproductive tissues, such as uterine tissues. There is room for an improved therapy for the treatment of such cancers, namely a SERM with no agonist properties on any reproductive tissues.

Cardiovascular disease is the leading cause of death among postmenopausal women. Until recently, the preponderance of data suggested that estrogen replacement therapy in postmenopausal women reduced the risk of cardiovascular disease, although some studies reported no beneficial effect on overall mortality. See, Barrett-Connor, E. et al., *The Potential of SERMs for Reducing the Risk of Coronary Heart Disease*, Trends Endocrinol. Metab., 1999, pp. 320–325, herein incorporated by reference. The mechanism(s) by which estrogens were believed to exert their beneficial effects on the cardiovascular system are not entirely clear. Potentially estrogen's effects on serum cholesterol and lipoproteins, antioxidant properties, vascular smooth muscle proliferation, and inhibition of arterial cholesterol accumulation were believed to play a role. *Id.* See also, Cosman, F., Lindsay, R. *Selective Estrogen Receptor Modulators: Clinical Spectrum*, Endocrine Rev., 1999, pp. 418–434, herein incorporated by reference. In light of the recent reports of the HERS II and WHI studies, however, continuous combined Hormone Therapy,

namely, CEE + MPA [Conjugated Equine Estrogen + Medroxy Progesterone Acetate], confers no cardiovascular benefit in menopausal women. See, Hulley S., Grady, D., Bush, T., et al., *Randomized trial of estrogen plus progestin for secondary prevention of coronary heart disease in postmenopausal women.* Heart and Estrogen/progestin Replacement Study (HERS) Research Group. J. *Am. Med. Assoc.* (1998) *280*:605–613 and Wassertheil-Smoller S., Hendrix, S.L., Limacher, M., et al., for the WHI Investigators. *Effect of estrogen plus progestin on stroke in postmenopausal women: the Women's Health Initiative: a randomized trial. JAMA* (2003) *289*, 2673–2684, each herein incorporated by reference with regard to such teaching). To what extent these findings may be extrapolated to SERMs is an issue that remains to be determined.

Other therapeutic alternatives include estrogen replacement therapy and/or hormone replacement therapy, which may be useful in the treatment of vasomotor symptoms, genitourinary atrophy, depression, and diabetes. Over 75% of women experience vasomotor symptoms during the climacteric years. Clinical signs, such as vasomotor symptoms and genitourinary atrophy, abate upon treatment with estrogen replacement therapy. Sagraves, R., *J. Clin. Pharmacol. (1995)*, 35*(9 Suppl):2S–10S*, herein incorporated by reference with regard to such teaching. Preliminary data suggest that estradiol may alleviate depression during perimenopause and that the combination of estrogens and selective serotonin reuptake inhibitors may alleviate depression during the postmenopausal period. Soares, C. N., Poitras, J. R., and Prouty, J., *Drugs Aging*, (2003), 20(2), 85–100, herein incorporated by reference with regard to such teaching. Furthermore, hormone replacement therapy may improve glycemic control among women with diabetes. Palin, S.L. et al., *Diabetes Research and Clinical Practice*, (2001), 54, 67–77; Ferrara, A. et al., *Diabetes Care*, (2001), 24(7), 1144–1150), each incorporated herein by reference with regard to such teaching. There is a need, however, for improved therapies that present better side effect profiles.

However, there are no conclusive data which allow the approval for treating a specific condition or disease selected from osteoporosis, osteoarthritis, breast cancer , rheumatoid arthritis, vasomotor symptoms, vulvar vaginal atrophy, and obesity in a mammal using the claimed compound.

The predictability or lack thereof in the art

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that the estrogen receptor modulation may impact on many non-reproductive tissues; however, specific estrogen receptor alpha (ERα) and estrogen receptor alpha (ERβ) may influence on some of the tissue-selective actions, not all kinds of tissues; this kind of treatment can not be translated into all the treatment of osteoporosis, osteoarthritis, breast cancer , rheumatoid arthritis, vasomotor symptoms, vulvar vaginal atrophy, and obesity in a mammal in regards to their therapeutic effects.

Hence, in the absence of a showing of correlation between all the above diseases claimed as capable of treating those conditions by modulating estrogen receptor alpha (ERα) and estrogen receptor alpha (ERβ) by means of the claimed compound, one of skill in the art is unable to fully predict possible results from the administration of the claimed compound due to the unpredictability of the role of treating

any above conditions, i.e. whether promotion or inhibition would be beneficial for the treatment of the above diseases.

The nature of pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The amount of direction or guidance present

The direction present in the instant specification is that the claimed compound can treat the condition or disease selected from osteoporosis, osteoarthritis, breast cancer , rheumatoid arthritis, vasomotor symptoms, vulvar vaginal atrophy, and obesity in a mammal. However, the specification is silent and fails to provide enough guidance as to whether the diseases listed in the above require the application of such a compound to the patient, i.e. the specification fails to provide a correlation between the diseases listed and the modulation of the estrogen specific receptor alpha (ERα) and estrogen receptor alpha (ERβ).

The presence or absence of working examples

There is no working example for the treatment of osteoporosis, osteoarthritis, breast cancer , rheumatoid arthritis, vasomotor symptoms, vulvar vaginal atrophy, and obesity in a mammal. Furthermore, there are not other working examples for any other diseases listed in the specification. Also, the compounds which are disclosed in the

specification have no pharmacological data regarding the treatment of all the above diseases. Also, the specification fails to provide working examples as to how the listed diseases can be treated by the modulation of the estrogen specific receptor alpha (ERα) and estrogen receptor alpha (ERβ).

The breadth of the claims

The breadth of the claims is that the claimed compound can treat the above diseases, without regards as to the affect of the modulation of the estrogen specific receptor alpha (ERα) and estrogen receptor alpha (ERβ) at the same time or different time on the stated diseases.

The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what listed diseases would be benefited by the affect of the modulation of the estrogen specific receptor and would furthermore then have to assess whether the claimed compound would provide treatment of the above diseases by way of influencing the estrogen specific receptors.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support of the broad use of the compound for the treatment of all the above diseases. As a result, necessitating one of skill to perform an exhaustive search for which diseases can be treated by the claimed compound in order to practice the claimed invention.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001 , states that " a patent is not a hunting license. It is not a reward for search , but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which diseases can be treated by the compound encompassed in the instant claims, with no assurance of success.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Primary Examiner
Art Unit :1625

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6/30/08